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Development and Evaluation of a Proactive Monitoring Model for Adverse Drug Events in Patients with Pulmonary Arterial Hypertension Based on the Delphi and Real-World Data

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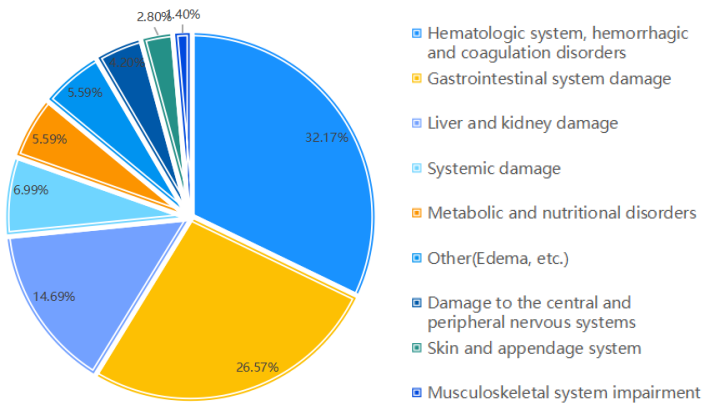
OBIECTIVEs: To develop and evaluate an innovative proactive monitoring model for adverse drug events (ADEs) in patients with pulmonary arterial hypertension (PAH), providing empirical support for rational medication use and improved health management.

METHODs: A framework of PAH-specific ADE triggers was established through two rounds of Delphi expert consultation and integrated into the China Hospital Pharmacovigilance System (CHPS) to build a proactive monitoring model. Electronic medical record (EMR) data from hospitalized PAH patients between January 1, 2022, and June 1, 2023, were collected. The model's performance was assessed using detection rate,sensitivity, specificity, and positive predictive value (PPV).

RESULTs: A total of 24 triggers were finalized, with 626 PAH patients included. All triggers generated positive activations; 22 successfully detected ADEs. A total of 472 positive triggers were recorded, averaging 0.75 per patient. The overall PPV was 30.30%. In total, 143 ADEs were identified in 110 patients, yielding a detection rate of 17.57%. Trigger sensitivity was 98.21%, specificity was 72.57%, and the Youden Index was 0.71. During the same period, spontaneous reporting identified only two ADE cases (0.32%), significantly lower than the model-based detection rate ($P < 0.001$).

Distribution of affected organs and systems in DE



CONCLUSIONs: The proactive monitoring model demonstrated strong performance in identifying ADEs among PAH patients. It offers a feasible,evidence-based approach to enhancing hospital pharmacovigilance and promoting safer, more rational drug use in clinical practice.

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